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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,095	10/19/2001	Moses V. Chao	CHAO=10A	6779

7590 08/29/2005

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EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,095	CHAO ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

DETAILED ACTION

Supplemental Action

1. After further consideration by the Examiner of the petition filed 4/28/05, and Applicants' argument that "it is clear that assay A is required and *always* performed in the presently [amended] claimed method while assays B, [B1 & B2] and C are optional... [and therefore] "are merely confirmatory assays for the critical assay A required in the presently claimed method" (i.e., does not create any additional search burden since assay A must be searched in all claims), the restriction requirement of 6/30/04 is withdrawn; thereby, making any decision on this petition moot. However, it is noted that should Applicants again amend the claims to separate assay A from assays B1, B2 and C, the restriction requirement would be re-instated.

2. It is again suggested that Applicants update the priority data in the first sentence of the specification, if they desire such priority to be granted.

3. Applicant's arguments filed 4/28/05 have been fully considered but they are not deemed to be persuasive.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-4 & 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in Paper NO: 20041101 & 20050707, and as follows.

The claims are not limited to only "transactivation" because base claim 1 alternatively recites in assay A "treating neuronal cells" with an "**activator**"; thereby, not accurately reciting the invention described within the specification, and alternatively, only confusing what the "claimed" invention entails. Similarly, base claim 1 still recites "treating *neuronal* cells with a candidate small molecule *activator*", yet then recites "to identify...**transactivation**"; thereby, further confusing what is actually being claimed.

Claims 4 & 8 remain indefinite because PC12 cells remain pheochromocytoma cells, and therefore, not "neuronal cells", as currently recited. Likewise, N2a neuroblastoma cells" remain tumor cells, and therefore, are not "neuronal cells"; thereby, keeping claims 4 & 8 indefinite. Therefore, Applicants' arguments that these cells "have all the characteristics of a neuronal cells line..." is simply incorrect, because extension of "processes" is not extension of dendrites or axons (i.e., neither PC12 cells nor N2a cells form synapses that is a property that characterizes neurons), and because neurons are not "immortal", which Applicants do acknowledge. Moreover, the teachings of Fan et al, Dickey et al., Greene et al. (and Prenzel et al.) have not been properly made of record in a properly executed IDS, and otherwise are simply not on point with the rejection of record.

It remains ambiguous what metes and bounds a "*small* molecule activator" entail, in which the term "**small**" in claim 1 **is a relative term** which renders the claim indefinite, by

definition. The term "small" is **not defined** by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Again, in contrast to Applicants' arguments on page 11 of the response that pages 16, 26 [pp 0047], 32, 35, and Table 1 on page 24 "teach" what metes and bounds constitute a small molecule, none of these pages define the term "small", and further fail to address this particular rejection. Note that this is not an enablement rejection, but a rejection under 112, second paragraph, where the specification fails to provide a closed-ended definition for the **relative term** "small", as previously made of record, and where Applicants' argument on page 11 that "such small molecules are of MW 1000 or less" has no basis within the specification, or within the claims.

It is again suggested that the third step of assay A be changed to "antibody to <u>the</u> [a] phosphorylated form..." to more accurately claim the current invention. Claims 4 & 8 can also be easily amended to obviate the rejection of these claims.

Claim 1 (assay C) is further indefinite and incomplete because "determining the *level* of cell survival" is also a relative term, which does not indicate whether cell survival is increased or decreased, in order to "identify" when a small molecule is a transactivator, or not. Likewise, claims 10 & 12 for assay B is indefinite and incomplete because it is unclear what steps are envisioned for determining when "an assessment" of a "relative level" and "extent of activation" are accomplished for these relative terms.

Lastly, similar to that previously made of record in Paper No: 20041101, it is ambiguous what exactly "detecting *specific* binding" entails (i.e., as it relates to claims 9 & 11), in that no

parameters defining what type of "*specific* binding" envisioned is recited in the claims. Nor is it clear when the relative term of "specific" is no longer specific; thereby, being indefinite.

6. Claims 1-4 & 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Clary et al. (U.S. Patent 5,753,225) for the reasons made of record in Paper NO: 20041101 & 20050707, and as follows.

As previously made of record, it is again noted that the term "small" is a relative term, which defines nothing, and does not distinguish the instant claims from the prior art. Likewise, the claims are not limited to only "transactivators", because base claim 1 (assay A) specifically recites "treating neuronal cells with a candidate small molecule *activator*", such as Clary's IgG antibody. Finally, because claim 1 also requires assay A alone, and because dependent claims 9-12 provide no further claim limitations to assay A, these claims are also anticipated by Clary et al., for the reasons made of record.

As also previously made of record, because base claim 1 fails to define what "neurotrophic receptor" is to be "transactivated", and because transactivating any neurotrophic receptor by directly activating trkA is encompassed by claims, the teachings of Clary encompass that currently claimed, because Clary et al teach all structurally recited steps within the current claims.

In summary, Clary et al teach a method of screening for molecules (e.g., small activators when compared to big molecules), in which the cell lysate of treated PC12 cells (i.e., as it relates to claim 4, and therefore, also to base claim 1) are reacted with the anti-phosphotyrosine TrkA monoclonal antibody, 4G10 (i.e., as it relates to claims 2 & 3; columns 28 & 27), and where the

relatively small molecule RtrkA.EX IgG is identified to phosphorylate the TrkA receptor, in the absence of the neurotrophin, NGF (i.e., as it relates to claim 1). Clary et al further teach decreased cell survival after both treating and culturing neonatal sympathetic neurons with RtrkA.EX IgG in Example 5 & Figure 3 in both the presence and absence of NGF (cols. 28-29; as it relates to assay C).

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
August 23, 2005

ROBERT C. HAYES, PH.D.
PRIMARY PATENT EXAMINER